



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JAN 10 1997

Mr. Karl Riedel  
Nature's Life  
M.K. Health Food Distributors, Inc.  
7180 Lampson Avenue  
Garden Grove, California 92841-3914

Dear Mr. Riedel:

This is in response to your letter of January 9, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your product, Sinus Ease.

Bromelain and quercetin help reduce swelling and the inflammatory response.  
Vitamin C has a mild antihistamine effect.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat or mitigate medical conditions of the sinuses. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.  
Acting Director,  
Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

cc:

HFA-224 (w/incoming)  
HFS-22 (CCO, KCarson)  
HFS-456 (r/f, Miles, Moore)  
HFS-450 (r/f)  
HFD-304 (Aronson)  
HFS-600 (Reynolds)  
r/d: C:\miles:1/15/97:C:\Miles\suppl\50589  
Initial: Rmoore 1/23/97  
Derfler 1/30/97  
f/d: C:\miles: 1/30/97: C:\Miles\Suppl\50589

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Elizabeth A. Yetley, Ph.D., Director  
Office of Special Nutritionals  
Food and Drug Administration  
HFS-450  
200 C Street SW  
Washington, DC 20204

January 9, 1997

We are using these nutritional support statements for these products:

**Horse Chestnut Seed Extract, 300 mg (code 682)**

Front panel: Strengthens capillary walls & reduces swelling in the legs\*

Side panel: Especially good for people who stand a lot, to help protect peripheral arteries, veins and capillaries which improves circulation in the legs.

**Sinus Ease, (code 665), containing bromelain, quercetin and vitamin C:**

Front panel: Nutritional support for sinuses.

Side panel: Bromelain and quercetin help reduce swelling and the inflammatory response. Vitamin C has a mild antihistamine effect.

**Magnesium malate, (code 659:**

Front panel: Magnesium promotes muscle relaxation.

Side panel: Magnesium promotes muscle relaxation and is needed for normal transmission of nerve impulses.

Sincerely,

Karl Riedel

cc. MK, DH, CM

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